JUN 1 2 2013

Summary of Safety and Effectiveness

Date: February 28, 2013

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Stefano Adami
Regulatory Affairs Manager
Phone: +390432945511

Product	Product Code	Regulation and Classification Name
SMR 3-Pegs Glenoids	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR 3-Pegs Glenoids are made from standard UHMWPE). They are intended for cemented fixation only.

The SMR 3-Pegs Glenoids are available in two sizes (Small and Standard). They are characterized by an articulating surface with a radius of curvature greater than the corresponding humeral head. This mismatch allows for translation of the head in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has three pegs for fixation in the glenoid.

The SMR 3-Pegs Glenoids are designed to articulate with the Limacorporate SMR humeral heads indicated for use in total shoulder replacement.

Intended Use:

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads only).

The Large Resection Stems (**not available in the US**) are indicated for oncology applications.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy

(disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.
In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.
The Anatomic glenoid construct consists of an all polyethylene glenoid or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	Use		Available in US
Anatomic	Reverse			Cem	Not Cem	
•	•	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X		•
•	•	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X	•
•	•	SMR Large Resection stems	Ti6Al4V	X		
•	•	SMR Modular Augments	Ti6Al4V	X		
•		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X	•
	•	SMR Reverse Humeral Body	Ti6Al4V	X	X	•
	•	SMR Reverse HA Coated Humeral Body	Ti6Al4V+HA		X	
•		SMR Humeral Heads (Standard, CTA)	CoCrMo	X	X	•
			Ti6Al4V	X	X	
•		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X	•
•	•	SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X	
	•	SMR Glenospheres	CoCrMo		X	•
			Ti6Al4V		X	
			UHMWPE X-Lima +Ti6Al4V		X	
	•	SMR Connectors	Ti6Al4V		X	•
	•	Reverse Liners	UHMWPE	X	X	•
			UHMWPE X-Lima	X	X	
			CoCrMo	X	X	
			Alumina	X	X	
•		SMR Cemented Glenoids	UHMWPE	X		•
•		SMR 3 Pegs Cemented Glenoids	UHMWPE X-Lima	X		
			UHMWPE	X		•
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*	•
			Ti6Al4V+PoroTi+HA		X	
•		SMR Metal Back Liner	UHMWPE	X*	X*	•
			UHMWPE X-Lima		X	
• *	•	SMR Bone screws	Ti6Al4V		X	•
	•	SMR Glenoid Plates	Ti		X	

Material Standards

Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – Ti (ASTM F67) - **UHMWPE** (ISO 5834-2 - ASTM F648) **Alumina** (ISO 6474) – **PoroTi Titanium Coating** (ASTM F1580) – **HA Hyroxyapatite Coating** (ISO 13779)

*NOTE :

- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **Outside the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for uncemented use with the addition of screws for fixation.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**

Predicate Devices:

- Limacorporate SMR Cemented Glenoids included in the following cleared 510(k):
  - SMR Cemented Shoulder System (K100858);
  - SMR Uncemented Shoulder System (K101263);
  - SMR CTA Humeral Heads (K110847);
  - SMR Revision Stems (K111212).
- Global Shoulder Crosslink Glenoid (DePuy, K052472);
- Glenoid Component for the Foundation Total Shoulder System (Encore - DJO, K960906).

Comparable Features to Predicate Device(s):

The intended use and indications for use for the Limacorporate SMR 3-Pegs Glenoids are similar to those of the referenced predicate devices and identical to those of the SMR cemented glenoids (K100858, K101263, K110847 – "*rotator cuff tear arthropathy*" and K111212 – "*revision of a failed primary component*"). As for all the referenced predicate devices where a glenoid component is used, the SMR 3-Pegs glenoids are used in total shoulder replacements and are intended for use with bone cement only.

The surface of the SMR 3-Pegs Glenoids articulating with the humeral heads and the spherical backside surface are identical to those of the already cleared SMR glenoids. As for all the referenced predicate devices, the SMR 3-Pegs glenoids have a radius of curvature greater than the radius of the articulating humeral heads. The three pegs used for the fixation by means of bone cement are very similar to those of Foundation Total Shoulder glenoid (Encore – DJO) and to the peripheral pegs of the Global Shoulder Crosslink glenoid (DePuy). The presence of grooves on the fixation peg has the same functionality (enhance cement adhesion) for SMR 3-Pegs Glenoids as for the other cemented glenoids of Limacorporate and for the Foundation Total Shoulder glenoid (Encore – DJO).

The UHMWPE used for the SMR 3-Pegs Glenoids is the same material used for the SMR System cemented glenoids (Limacorporate). The two sizes of glenoids available for the SMR 3-Pegs Glenoids have the same identical dimensions of the sizes Small and Standard of the cleared SMR cemented glenoids.

All SMR 3-Pegs Glenoids and referenced Predicate Devices are sterile, single use devices. Sterilization of the SMR 3-Pegs Glenoids performed by means of ethylene oxide (EtO), the Sterility Assurance Level (SAL of 10^{-6}), the shelf life of 5 years are identical to that of the cleared cemented glenoids of the SMR Systems.

Non-Clinical Testing:
The SMR 3-Pegs Glenoid has undergone mechanical tests according to ASTM F1829 (*Standard Test Method for Static Evaluation of Glenoid Locking Mechanism in Shear*) and ASTM F2028 (*Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation*). A Range of Motion simulation has been performed to ensure the device design does not overly limit range of motion. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing:
Clinical testing was not necessary to demonstrate substantial equivalence of the SMR 3-Pegs Glenoids to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter Dated: June 12, 2013

Limacorporate S.p.A.
% Hastings Regulatory, LLC
Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590

Re: K130642
Trade/Device Name: SMR 3-Pegs Glenoids
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: May 4, 2013
Received: May 6, 2013

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne -A

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130642
Device Name: SMR 3-Pegs Glenoids
Indications for Use:

SMR 3-Pegs Glenoids
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The Anatomic glenoid construct consists of an all polyethylene glenoid or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	Use		Available in US
Anatomic	Reverse			Cem	Not Cem	
•	•	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X		•
•	•	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X	•
•	•	SMR Large Resection stems	Ti6Al4V	X		
•	•	SMR Modular Augments	Ti6Al4V	X		
•		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X	•
	•	SMR Reverse Humeral Body	Ti6Al4V	X	X	•
	•	SMR Reverse HA Coated Humeral Body	Ti6Al4V+HA		X	
•		SMR Humeral Heads (Standard, CTA)	CoCrMo	X	X	•
			Ti6Al4V	X	X	
•		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X	•
•	•	SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X	

System		Components	Material	Use		Available in US
Anatomic	Reverse			Cem.	Not Cem	
	•	SMR Glenospheres	CoCrMo		X	•
			Ti6Al4V		X	
			UHMWPE X-Lima +Ti6Al4V		X	
	•	SMR Connectors	Ti6Al4V		X	•
	•	Reverse Liners	UHMWPE	X	X	•
			UHMWPE X-Lima	X	X	
			CoCrMo	X	X	
			Alumina	X	X	
•		SMR Cemented Glenoids	UHMWPE	X		•
•		SMR 3 Pegs Cemented Glenoids	UHMWPE X-Lima	X		
		SMR 3 Pegs Cemented Glenoids	UHMWPE	X		•
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*	•
			Ti6Al4V+PoroTi+HA		X	
•		SMR Metal Back Liner	UHMWPE	X*	X*	•
			UHMWPE X-Lima		X	
•	•	SMR Bone screws	Ti6Al4V		X	•
	•	SMR Glenoid Plates	Ti		X	

Material Standards

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices